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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/625,803	07/26/2000	Robert A. Rabiner	11010/18	8247

29934 7590 03/01/2004

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EXAMINER	
MANTIS MERCADER, ELENI M	
ART UNIT	**PAPER NUMBER**
3737	13

DATE MAILED: 03/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/625,803	Applicant(s) RABINER ET AL.
	Examiner Eleni Mantis Mercader	Art Unit 3737

-- Th MAILING DATE of this communication appears on the cover sheet with th correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-28,49-60 and 63-82* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-28, 49-60 and 63-82* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 1-15, 17-28, 49-60 and 63-82 have been considered but are moot in view of the new ground(s) of rejection. The new grounds of rejection are the amendments stating: "an at least one aspiration channel recessed along the length of an outer surface of the ultrasonic probe wherein aspiration occurs through the at least one aspiration channel along the length of the ultrasonic probe."

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 17-28, 49-60, and 63-82 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-37 of U.S. Patent No. 6,524,251. Although the conflicting claims are not identical, they are not patentably distinct from each other because they represent obvious alternate variations

and groupings of the patented claims, which include transverse vibration and aspiration means.

4. Claims 17-28, 49-60, and 63-82 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-40 of U.S. Patent No. 6,660,013. Although the conflicting claims are not identical, they are not patentably distinct from each other because they represent obvious alternate variations and groupings of the patented claims, which include transverse vibration and aspiration.

5. Claims 17-28, 49-60, and 63-82 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-37 of U.S. Patent No. 6,652,547. Although the conflicting claims are not identical, they are not patentably distinct from each other because they represent obvious alternate variations and groupings of the patented claims, which include transverse vibration and aspiration.

6. Claims 17-28, 49-60, and 63-82 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 6,679,873. Although the conflicting claims are not identical, they are not patentably distinct from each other because they represent obvious alternate variations and groupings of the patented claims, which include transverse vibration and aspiration.

7. Claims 17-28, 49-60, and 63-82 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-28 of U.S. Patent No. 6,695,781 (note that this patent is not available for printing in WEST so please see application serial no. 09/917,471). Although the conflicting claims are not identical, they are not patentably distinct from each other because they represent obvious alternate

variations and groupings of the patented claims, of which the claimed language includes the features of transverse vibration and aspiration means.

8. Claims 17-28, 49-60, and 63-82 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8, 11-13, 19-27, 30-32, 38-46, 49-51, 57-65, 68-70, and 76-77 of copending Application No. 10/071,953. Although the conflicting claims are not identical, they are not patentably distinct from each other because they represent obvious alternate variations and groupings of the presented claims in Application No. 10/071,953 including ultrasonic therapy via transverse vibration and an aspiration passage between the probe and the sheath.

Furthermore, it would have been obvious to one skilled in the art at the time that the invention was made to have utilized the apparatus and procedure at any desired area of interest for destruction and removal of the tissue of interest. Therefore, it would have been obvious to one skilled in the art at the time that the invention was made to have emulsified and/or fragmented the tissue of interest such as destruction of cancer cells in the uterus.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Claims 17-28, 49-60, and 63-82 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-76 of copending Application No. 10/268,487. Although the conflicting claims are not identical, they are not patentably distinct from each other because they represent obvious

alternate variations and groupings of the presented claims in Application No. 10/268,487 including ultrasonic therapy via transverse vibration and an aspiration channel.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claims 17-28, 49-60, and 63-82 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 28-59 of copending Application No. 10/268,843. Although the conflicting claims are not identical, they are not patentably distinct from each other because they represent obvious alternate variations and groupings of the presented claims in Application No. 10/268,843 including ultrasonic therapy via transverse vibration and an aspiration channel.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. Claims 17-28, 49-60, and 63-82 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-60 of copending Application No. 10/371,781. Although the conflicting claims are not identical, they are not patentably distinct from each other because they represent obvious alternate variations and groupings of the presented claims in Application No. 10/371,781 including ultrasonic therapy via transverse vibration and an aspiration channel.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Claims 17-28, 49-60, and 63-82 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of copending Application No. 10/373,134. Although the conflicting claims are not

identical, they are not patentably distinct from each other because they represent obvious alternate variations and groupings of the presented claims in Application No. 10/373,134 including ultrasonic therapy via transverse vibration and having an aspiration channel.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

13. Claims 17-28, 49-60, and 63-82 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-68 of copending Application No. 10/396,914 in view of Soble et al.'724. Although the conflicting claims are not identical, they are not patentably distinct from each other because they represent obvious alternate variations and groupings of the presented claims in Application No. 10/396,914 including ultrasonic therapy via transverse vibration. The claims of Application No. 10/396,914 do not expressly state the use of aspiration channels. In the same field of endeavor, Soble et al.'724 teach at least one aspiration channel recessed along the length of an outer surface of the probe, wherein aspiration occurs through the at least one aspiration channel along the length of the probe (see col. 6, lines 9-27). It would have been obvious to one skilled in the art at the time that the invention was made to have modified the claims of Application No. 10/396,914 to incorporate channels for aspiring any fragments remaining in the treatment area.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

14. Claims 17-28, 49-60, and 63-82 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of copending Application No. 10/462,182. Although the conflicting claims are not

identical, they are not patentably distinct from each other because they represent obvious alternate variations and groupings of the presented claims in Application No. 10/462,182 including ultrasonic therapy via transverse vibration and having an aspiration channel.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

16. Claims 17-24, 26-28, 49-58 and 49-60 are rejected under 35 U.S.C. 102(e) as being anticipated by Soble et al.'724.

Soble et al.'724 teach all the features of the instant invention including an ultrasonic treatment apparatus having:

A therapeutic probe for use as a lithotripsy including using an ultrasound probe having an ultrasonic tip, the ultrasonic probe including at least one channel on an outer surface of the ultrasonic probe, the at least one channel extending from the proximal end of the ultrasonic probe to a location adjacent the ultrasonic probe (see col. 1, lines 54-65; describing the use of ultrasound as a possible lithotripter and see col. 2, lines 48-52; describing use of a lithotripter through the probe). The ultrasonic probe includes an irrigation passage (see col. 2, lines 36-41). The sheath of the probe has multiple lumens

(see col. 3, lines 18-29). The possible axial arrangement of the parts and their interconnections are depicted in Figures 3A-3C.

Soble et al.'724 teach a fiberoptic endoscope having channels for insertion of treating tools including a therapeutic lithotripter probe (see col. 2, lines 42-56).

Soble et al.'724 teach at least one aspiration channel recessed along the length of an outer surface of the probe, wherein aspiration occurs through the at least one aspiration channel along the length of the probe (see col. 6, lines 9-27).

Soble et al.'724 teach the use of a flexible endoscope and lithotripter as well as a flexible sheath (see col. 2, lines 42-56 and col. 5, lines 45-53).

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

18. Claims 63-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soble et al.'724 in view Sakurai et al.'144.

Soble et al.'724 teach all the features of the instant invention including an ultrasonic treatment apparatus having:

A therapeutic probe for use as a lithotripsy including using an ultrasound probe having an ultrasonic tip, the ultrasonic probe including at least one channel on an outer surface of the ultrasonic probe, the at least one channel extending from the proximal end of the ultrasonic probe to a location adjacent the ultrasonic probe (see col. 1, lines 54-65; describing the use of ultrasound as a possible lithotripter and see col. 2, lines 48-52;

describing use of a lithotripter through the probe). The ultrasonic probe includes an irrigation passage (see col. 2, lines 36-41). The sheath of the probe has multiple lumens (see col. 3, lines 18-29). The possible axial arrangement of the parts and their interconnections are depicted in Figures 3A-3C.

Soble et al.'724 teach a fiberoptic endoscope having channels for insertion of treating tools including a therapeutic lithotripter probe (see col. 2, lines 42-56).

Soble et al.'724 teach at least one aspiration channel recessed along the length of an outer surface of the probe, wherein aspiration occurs through the at least one aspiration channel along the length of the probe (see col. 6, lines 9-27).

Soble et al.'724 teach the use of a flexible endoscope and lithotripter as well as a flexible sheath (see col. 2, lines 42-56 and col. 5, lines 45-53).

Soble et al.'724 do not expressly teach the probe supporting transverse ultrasonic vibration along at least a portion of the axial length of the probe and wherein the vibration of the probe provides a plurality of anti-nodes along at least a portion of the axial length.

In the same field of endeavor, Sakurai et al.'144 teach the probe supporting transverse ultrasonic vibration along at least a portion of the axial length of the probe and wherein the vibration of the probe provides a plurality of anti-nodes along at least a portion of the axial length (in Figure 13, see how the horn (element 63) transmits the vibrations to the ultrasonic probes (elements 61 or 62) with the transverse oscillation of the probe indicated in Figures 40 and 41 with indications of anti-node or loops wherein there is maximum oscillation along the length of the probes).

It would have been obvious to one skilled in the art at the time that the invention was made to have modified Soble et al.'724 in view of Sakurai et al.'144 and incorporated the specific teachings of Sakurai et al.'144 by using the specific probe as the probe of choice in lithotripsy by utilizing transverse vibration as this is such an ultrasonic device (see in col. 1, lines 12-16, describing use of device for breaking stones).

Conclusion

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eleni Mantis Mercader whose telephone number is 703 308-0899. The examiner can normally be reached on Mon. - Fri., 8:00 a.m.-6:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dennis Ruhl can be reached on 703 308-2262. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Eleni Mantis Mercader
Primary Examiner
Art Unit 3737

EMM